THE VETERANS HEALTH ADMINISTRATION (VHA)

Report to the Office of Special Counsel (OSC)

OSC File Number DI-12-3816

G.V. (Sonny) Montgomery Department of Veterans Affairs (VA) Medical Center

Jackson, MS

Report Date: June 21, 2013

Executive Summary

Summary of Allegations

At the direction of the Secretary, the Under Secretary for Health requested that the Office of the Deputy Under Secretary for Health for Operations and Management send a team of subject matter experts to investigate a complaint filed with the Office of Special Counsel (OSC) by Dr. Phyllis Hollenbeck, a primary care physician and Whistleblower, at the G.V. (Sonny) Montgomery Department of Veterans Affairs (VA) Medical Center in Jackson, Mississippi (hereafter, the Medical Center). Dr. Hollenbeck asserts that employees are, or have, engaged in misconduct that may constitute a violation of law, rule, or regulation, gross mismanagement, and abuse of authority that may create a substantial and specific danger to public health and safety at the Medical Center. The Whistleblower alleged, in brief, that:

- The Medical Center did not have a sufficient number of physicians in the Primary Care Unit (PCU), resulting in failure to provide adequate care for patients and proper supervision of Nurse Practitioners (NP), who provide the majority of patient care services (Allegation #1);

- Inadequate physician staffing levels resulted in failure to properly supervise NPs, which violates state licensure agreements, resulting in NPs practicing without proper certification (Allegation #2);

- Inadequate physician staffing levels resulted in numerous fraudulently completed Centers for Medicare and Medicaid Services (CMS) home health certifications/forms for patients (Allegation #3); and

- Narcotics were improperly prescribed, e.g., physicians prescribe narcotics for patients they had not treated (Allegation #4).

The investigative review team conducted a site visit at the Medical Center from April 15, 2013, through April 19, 2013, and reviewed submitted documents; a second site visit was conducted by select team members on May 7 and May 8, 2013 to obtain and review additional staffing-related documents.

Conclusions for Allegations #1 and #2

Due to the complexities and interconnectedness of allegations #1 and #2, the team elected to investigate and dissect the two allegations concomitantly, including the findings and recommendations for both.

- The review team substantiates that the Medical Center does not have a sufficient number of physicians in the PCU and NPs have not had appropriate supervision/collaboration with Physician Collaborators.

  The review team did not substantiate that inadequate care was provided (even with the noted scheduling problems). It is the professional expert opinion of the review team that there are enough problematic indicators present to suggest there may be quality of care issues that require further review. Although the review team found that all NPs have requisite certifications and licenses, NPs in the PCU were erroneously declared as Licensed Independent Practitioners (LIP), and the required monitoring of their practice did not consistently occur resulting in NPs practicing outside the scope of their licensure.

- The Medical Center's policy permitting NPs to practice as LIPs when that practice is not authorized by their individual state Practice Acts violates VHA policy. Only the two NPs licensed in Iowa are allowed to practice as LIPs.

- Granting NPs clinical privileges when they are not LIPs violates VHA policy. Only the two Primary Care NPs licensed in Iowa are allowed to be granted clinical privileges; all others must have a scope of practice.

- There is a lack of understanding among Medical Center leadership regarding NP practice and licensure requirements. This is evident by the fact that leadership erroneously declared NPs as LIPs and granted clinical privileges, yet they have also stipulated that NPs must have collaborative agreements per individual state licensing board requirements. This is further confounded by the fact that, despite requiring collaborative agreements (which is the correct approach), leadership has not implemented a process for ensuring all required collaborative agreements are in place, and the appropriate monitoring of NP practice by Physician Collaborators occurs.

- Ten of the 13 NPs currently practicing at the Medical Center and whose licenses require collaborative agreements have an approved collaborative agreement in place.

- Many, if not most, of the Primary Care NPs have not complied with state licensing board requirements for ensuring their practice is appropriately monitored by their Physician Collaborators, such as chart reviews and face-to-face meetings with the Physician Collaborator. In addition, the Medical Center has no process in place to ensure monitoring requirements are met.

- State requirements vary as to the appropriate ratio between NPs and a Physician Collaborator. Some states set no MD-to-NP ratio requirement. Others establish a ratio of 1:3, 1:4, or more. There should be a reasonable limit to the number of NPs per Physician Collaborator to ensure appropriate medical direction and supervision by the Physician Collaborator is provided, consistent with the terms

of the collaborative agreements. We are aware that in March 2013, the Mississippi Board of Medical Licensure amended Rule 1.3 of Chapter 1 of Part 2630 of the Mississippi Administrative Code to state, in relevant part: "Any one Physician should have no more than four collaborative agreements." [See Mississippi Administrative Code, Part 2630, Chapter 1, Rule 1.3], Requirements for collaborating physicians, which states: "Physicians are prohibited from entering into primary collaborative agreements with more than four Advanced Practice Registered Nurses at any one time unless a waiver is expressly granted by the Board for that particular collaborative agreement." According to a notice on the Board of Medical Licensure's Web site, implementation of the amendment is suspended until July 31, 2013. The consensus among team members is that the ratio should be limited to four or five NPs to one Physician Collaborator. Clearly, the one Medical Center Physician Collaborator, who has 14 current collaborative agreements, is in violation of this state requirement.

- All Medical Center PCU NPs currently have the required state NP licenses and national NP certifications.

- There was no evidence to indicate that the former Chief of Staff, Dr. Kent Kirchner, had 160 collaborative agreements, as alleged by the Whistleblower. The review team found evidence that Dr. Kirchner had only four collaborative agreements with Primary Care NPs during the review period of 2010 to present.

- The Medical Center PCU has an insufficient number of physicians.

- The NPs in the PCU have panel sizes that generally exceed VHA guidelines.

- Clinical quality data, available Ongoing Professional Practice Evaluation data, and the fact that only one provider has been reported to the National Practitioner Data Bank since October 1, 2010, for either a tort claim settlement or an adverse action against clinical privileges relating to the quality of care, are indicators that the Medical Center PCU staff is providing quality care. However, the following additional problematic indicators led the review team to conclude further review of the following needs to be conducted in order to explicitly declare that appropriate and adequate high quality care has been provided in the Medical Center PCU:

    - Insufficient physician staffing;
    - Sporadic tenure of Locum Tenens physicians;
    - NPs functioning as LIPs, when in fact they are not;
    - Failure to appropriately monitor the clinical practice of NPs;
    - Lack of timely response by providers to Computerized Patient Record System View Alerts;
    - Multiple patient appointment scheduling problems (e.g., double books, Vesting Clinic/Ghost Clinic); and

- Large volume of patient complaints regarding access to, and timeliness of, care

- The Medical Center NPs appear to be appropriately identifying themselves as NPs to their patients.

In summary, the team substantiates the Medical Center does not have a sufficient number of physicians, and NPs have not had appropriate supervision and collaboration with Physician Collaborators. The team did not substantiate that inadequate care was provided even with the noted scheduling problems. However, there are enough problematic indicators present to suggest there may be quality of care issues that require further review. Although the team found that all NPs currently have requisite NP certifications and licenses, NPs in the PCU have been erroneously declared as LIPs, and the required monitoring of their practice has not consistently occurred. NPs were potentially practicing outside the scope of their licensure and not appropriately monitored by Physician Collaborators.

Recommendations for Allegations #1 and #2

- The Medical Center leadership must immediately correct the erroneous declaration that all NPs will practice as LIPs.

- Medical staff bylaws must be amended to indicate that NPs are considered LIPs only when their state licensure permits or VA policy changes occur.

- The Medical Center leadership must immediately implement scopes of practice versus clinical privileges for NPs, who are not permitted to practice as LIPs.

- The Medical Center leadership must immediately ensure that all NPs who require collaborative agreements, in fact have them, and that they are approved by the NP's respective state licensing board.

- The Medical Center leadership should ensure the equitable distribution of collaborative agreements among physicians, and a reasonable limitation should be placed on the number of collaborative agreements for any one physician. If a state's Nursing Practice Act establishes a limitation on the number of collaborative agreements that a collaborating supervising physician may have with an NP at any one time, then the Medical Center needs to comply with such requirements.

- The Medical Center leadership should eliminate use of Locum Tenens physicians in the PCU to the extent possible.

- Locum Tenens physicians should not be allowed to be Physician Collaborators because of their short tenure.

- The Medical Center leadership must immediately implement a process to ensure that appropriate monitoring of NP practice by Physician Collaborators occurs and is documented in accordance with state licensure requirements.

- The Medical Center leadership must continue to aggressively work to hire permanent full-time physicians for the PCU to obtain an NP:MD ratio of 1:1. Once an adequate number of physicians is hired, the facility should reduce panel sizes for NPs to meet Veterans Health Administration (VHA) guidelines.

- The Medical Center leadership should consult the Office of Workforce Management and Consulting in VA Central Office to ensure they are utilizing all available resources to recruit primary care physicians.

- The Medical Center leadership should eliminate the use of Ghost Clinics. All clinics must have an assigned provider.

- The Medical Center leadership should eliminate the use of overbooked and double-booked appointments to the extent possible. The Medical Center leadership needs to implement the principles of open access scheduling, which means patients receive care when and where they want or need, including on the same day if so requested.

- The Medical Center must convert six-part credentialing and privileging folders to the electronic VetPro system, as required by VHA leadership.

- Veterans Integrated Service Network (VISN) 16 leadership should arrange for an external clinical quality review of all primary care at the Medical Center, particularly in light of the evidence that electronic View Alerts were often not being reviewed by physicians in a timely fashion, and NPs were practicing outside the scope of their licensure. The Medical Center should conduct a clinical care review of a representative sample of the patient care records for all 42 NPs, as well as all physicians, who worked in the PCU from January 1, 2010, to present. The VISN should work with facility leadership to determine the sample size needed to ensure that the quality of care delivered by all of these providers was appropriate. If any clinical care issues are identified, the facility should consider expanding the sample. Specific cases involving unresolved questions as to quality of care should be referred to the Office of the Medical Inspector for further investigation.

- VISN 16 leadership should actively assist the Medical Center to implement these recommendations (and any others it deems necessary to ensure quality care is consistently rendered and available to PCU patients) through an approved action

plan; and be responsible for submitting the action plan to the Under Secretary for Health along with periodic status reports (through to completion of all items).

- VHA should consider issuing an Information Letter (IL) to reinforce across the system the need for compliance with both NP state licensure requirements and with national policies on NP credentialing, privileging, and scopes of practice. Such guidance should identify Regional Counsel as an important resource for the facilities as they review program compliance requirements.

Allegation #3: Inadequate Staffing Results in the Improper Completion of Medicare Home Health Certificates/Forms

Conclusion for Allegation #3

The team cannot substantiate the allegation that CMS home health certificates/forms are/were completed inappropriately and in violation of Federal law because the Medical Center's PCU staff has not followed statutory and regulatory requirements of the Medicare home health program. However, the team cannot rule out that the allegation may have some merit given the noted statements of interviewees and the team's substantiation of allegations related to the lack of supervision of NPs and the lack of necessary collaborative agreements between collaborating physicians and the NPs.

Recommendation for Allegation #3

To determine whether Medicare home health certification forms are/were being appropriately completed by the PCU providers, VHA should task the appropriate VHA offices, e.g., the VHA Office of Compliance and Business Integrity and the Office of Patient Care Services, Home Health Program, to work together to conduct a random check of Medical Center PCU patient charts to determine if any Medicare forms are present, and if so, whether they were completed appropriately. Such findings need to be reported to the VHA Under Secretary for Health, who will then need to consider if any follow-up action is necessitated. Additionally, facility leadership should consider development of a training and educational module for completion of these forms to ensure PCU and other staff are aware of Medicare compliance requirements.

Allegation #4: Facility Uses Improper Procedures for Issuing Narcotics Prescriptions

The team fully substantiates the allegation that past Medical Center management advised its NPs, most of whom are licensed in Mississippi, that they did not need to obtain individual (Drug Enforcement Administration (DEA) registration or file it with the Mississippi Board of Nursing (BON), since they could rely on the institutional registration

with a suffix. Further, the team found that the allegation that NPs in the PCU, including "grandfathered" NPs, were allowed to write narcotics prescriptions under the facility's institutional DEA registration number, which is in violation of Federal and State law.

Conclusions for Allegation #4

- Medical Center leadership was under the impression that all providers were allowed to use the institution's generic DEA number, as long as the provider was working within the scope of a VA provider. In fact, as explained above, as a matter of Federal law and VA policy, where a practitioner's state of licensure requires individual DEA certification in order to be authorized to prescribe controlled substances, the practitioner may not be granted prescriptive authority for controlled substances without such individual DEA certification. Thus, with respect to NPs whose state of licensure required individual DEA certification to prescribe controlled substances, we substantiated the Whistleblower's allegations that the Medical Center's practice violated Federal law and VA policy.

- As of the writing of this report, all NPs are licensed as an NP in a state and are certified nationally as an adult or family practice NP, including the two NPs still at the Medical Center, who were originally grandfathered in from the NP licensure requirement. Grandfathered in NPs are not exempt from meeting any additional requirements by their state of licensure for obtaining prescriptive authority for controlled substances.

- When management was made aware that not all NPs were authorized by their license to write prescriptions for controlled substances, they took immediate action to stop the practice and attempted to put the prescribing back in the hands of staff physicians. The team confirmed that some, but not all, staff physicians agreed to renew prescriptions based on a records review alone; thus, we substantiated the whistleblower's allegations.

- When management learned that this practice was also improper because a face-to-face physician/patient encounter was required, they created the Locum Tenens clinic as a stop gap measure. Patients were physically seen by these physicians, and prescriptions written appropriately. These clinics continued until the NPs obtained their own DEA certificates. Current prescribing practices comply with Federal law and VHA policy.

Recommendations for Allegation #4

- The three NPs who have not yet received their individual DEA certificates should be encouraged to obtain them as soon as possible. Until that time, the NPs should not write prescriptions for controlled substances, and should rely on the collaborating physicians to write these prescriptions, as necessary.

- The NP functional statement, qualification standards, and dimensions of practice of the facility must be revised to be consistent with national policy per VA Handbook 5005, Appendix G6.

- The facility must complete a clinical care review of a random sample of the patient care records for the NPs who were prescribing controlled substances, outside of the authority granted by their license. This review should focus on patients who were actually prescribed controlled substances. A sample of at least 10 percent should be completed. If any clinical issues are identified, the review should be expanded.

- Facility policies and bylaws concerning the practice of NPs should be updated, to reflect VA national policies and the licensure and DEA requirements for this profession. Functional statements should be updated to reflect all current regulations.

Summary Conclusion

In conclusion, the team determined that certain Federal laws and regulations, as well as state laws, may have been violated. These are outlined in detail in the report. Additionally, the team determined that due to mismanagement, both VA and VHA policy may not have been followed, specifically credentialing and privileging and VHA outpatient scheduling processes and procedures. While no changes in agency rules, regulations, or practices should be taken as a result of this investigation, the fact-finding team made a number of recommendations for the Medical Center to adhere to/or enforce current rules, regulations, practices, and policies, as noted in the report and summarized in this Executive Summary. There was no evidence of abuse of authority; however, the team found potential liability from failure to follow VHA policies and procedures, specifically related to the PCU and physician oversight. Recommendations are made to ensure clinical reviews are conducted by VISN 16, which oversees the Medical Center to ensure the PCU complies with all applicable laws and VHA policies to maintain a high quality, safe health care environment for patient care.

Department of Veterans Affairs (VA)
Jackson VAMC Primary Care Provider Safety Report
December 2010-April 2013

Attachmen

NP Name	Employment Status C=Current employee at JVAMC in PC CJ= Current employee at JVAMC not in PC NC= No longer employed at JVAMC	State of Licensure	NP License Original Date	NP Type Certification/ Date	CA Required Y or N	CA in Place Y or N	CA Date Current	CA Date Original	Collaborating MD/ work location	Individual DEA and issue date	NPDB Y or N
Abernathy, Sarah	CJ	MS	11/30/94	ANCC Family 12/1/94	Y	Y	10/11/12	12/00/10	Jessie Crawford Moorefield Jackson VAMC	6/26/12	N
Alderson, Joy	C	NC	1/24/98	ANCC Family 9/1/96	Y	Y	12/31/12	12/00/10	Safi Sobhy Soliman Fayetteville NC VAMC	N	N
Alford, Donna	CJ	MS	2/12/96	ANCC Adult/Ger 9/1/95	Y	Y	12/18/12	12/9/10	Jessie Crawford Moorefield Jackson VAMC	7/19/12	N
Anderson, Dora	CJ	MS	4/27/99	ANCC Family 12/1/98	Y	Y	12/15/12	12/7/10	Ronald Braswell Jackson VAMC	5/3/11	N
Anderson, Marie	C	MS	1/9/95	ANCC Family 12/1/94	Y	Y	3/22/13	12/21/10	Nikesia Beamon-Webb Jackson VAMC	1/9/13	N
Barham, Jennifer	CJ	MS	12/2/02	ANCC Acute Care 12/1/01	Y	Y	12/12/12	12/30/10	Carla Cole Hewitt Jackson VAMC	N	N
Beal, Monifa	CJ	MS	4/13/10	ANCC Family 3/15/10	Y	Y	12/5/12	9/7/11	Charlotte Scott-Bennett Jason Taylor Jackson VAMC	8/10/12	N
Bowman-Bingham , Kellie	C	MS	7/26/06	AANP Family 7/1/06	Y	Y	12/14/12	12/14/10	Nikesia Beamon-Webb Jackson VAMC	12/28/12	N

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Brewster, Rebecca	NC	TN	8/13/04	ANCC Family 2/1/08	Y for Rx authority	N	N/A	N/A	N/A	12/7/06	N
Brown, Ginger	C	MS	12/16/93	ANCC Family 12/1/93	Y	Y	3/17/13	12/9/10	Jessie Crawford Moorefield Jackson VAMC	5/4/12	N
Bullie, Bianca	C	MS	12/9/11	AANP Family 11/1/11	Y	Y	10/30/12	2/7/12	Nikesia Beamon-Webb Jackson VAMC	1/16/13	N
Capps, Mark	NC	FL	3/5/03	ANCC Family 4/1/98	Y	Y - expired last 8 months of employ ment	Left Jackson 1/31/13- CA had expired 5/31/12	6/1/11	William Rummel Milton, FL		N
Christmas, Sandra	CJ	MS	4/8/09	ANCC Family 3/16/09	Y	Y	10/22/12	12/7/10	Tammy Sims Sanders Jackson VAMC	N	N
Clanton, Rebecca	C	MS	6/18/04	AANP Family 6/1/04	Y	Y	12/27/12	12/14/10	Jessie Crawford Moorefield Jackson VAMC	7/11/11	N
Denson, Ruby	CJ	MS	12/6/95	ANCC Family 12/1/95	Y	Y	11/6/12	12/9/10	Brendan Ross and Pamela Graham - Jackson VAMC	6/27/12	N
Dunn, Robert	CJ	MS	6/1/11	ANCC Family 9/1/07	Y	Y	3/22/13	7/19/12	Kent Kirchner Jackson VAMC	N	N
Emerson, Delia	C	MS	6/28/05	ANCC Family 7/13/05	Y	Y	12/14/12	12/13/10	Donald Butcher (Locums) no longer employed at Jackson VAMC	4/27/13	N

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Evans, Sherrill	NC	MS	2/24/97	ANCC Family 4/1/97	Y	Y	Left Jackson 8/25/12-CA still in effect	12/7/10	Kent Kirchner Jackson VAMC	8/27/12	N
Franklin, Rose	C	MS	9/11/07	ANCC Family 9/11/07	Y	Y	11/13/12	12/16/10	Nikesia Beamon-Webb Jackson VAMC	8/2/11	N
Haney, Valerie	NC	MS	6/3/11	ANCC Family 10/1/01	Y	Y	Left Jackson 8/11/12-CA still in effect	7/19/12	Rachel Thornton Jackson VAMC	N	N
Hardwick, Penny	C	IA	4/10/13	ANCC Family 12/1/94	Y[1]	N	N/A	N/A	N/A	3/29/13	N
Holt, Stephanie (CJ)	CJ	MS	9/1/04	ANCC Family 9/1/04	Y	Y	3/20/13	12/13/12	Jessie Crawford Moorefield Jackson VAMC	N	N
Hubbard, William	C	MS IA	12/24/08 1/18/13	ANCC Family 4/28/08	Y[2]	N[3]	12/14/12	12/13/10	Donald Butcher (Locums) no longer employed at Jackson VAMC	4/1/13	N
Jackson, Maybelle	CJ	MS	8/22/97	ANCC Family 9/1/97	Y	Y	12/6/12	12/9/10	Jessie Crawford Moorefield Jackson VAMC	N	N
Jett, Michelle	CJ	MS	11/28/95	ANCC Family 12/1/95	Y	Y	12/19/12	12/8/10	Eric Undesser Jackson VAMC	12/22/10	N
Kendrick, Barbara	C	MS	9/9/04	ANCC Family 8/1/04	Y	N[3]	2/26/13	12/8/10	Donald Butcher (Locums) no longer employed at Jackson VAMC	1/9/13	N

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Liberto, Christine	NC	MS	12/21/94	ANCC Adult 12/1/94	y	y	Left Jackson 6/23/12- CA still in effect	12/7/10	Nikesia Beamon-Webb Jackson VAMC	N	N
Lofton, Grant	CJ	MS	12/18/97	ANCC Family 9/1/97	Y	Y	3/26/13	12/17/10	Ronald Braswell Jackson VAMC	N	N
Mack, Linda	CJ	MS	9/1/12	ANCC Family 9/1/97	Y[4]	Y	3/22/13	3/22/13	Kent Kirchner Jackson VAMC		N
McDonald, Irvin	NC	MS	Grandfather	AANP Family 12/1/99	Y for Rx authority	Y	12/9/10	12/9/10	Jessie Crawford Moorefield Jackson VAMC	N	N
McKinney, Kathleen	C	OH	3/24/05	ANCC Family 4/1/04	Y	N[5]	4/29/13	4/29/13	Chelsea Jones Jackson VAMC	N	N
Owens, Sylvia	C	MS	4/10/09	ANCC Family 1/26/09	Y	Y	10/30/12	12/7/10	Nikesia Beamon-Webb Jackson VAMC	2/27/13	N
Ransberg-Garner, Carolyn	CJ	MS	12/17/98	ANCC Family 12/1/98	Y	Y	11/18/12	12/13/10	Jessie Crawford Moorefield Jackson VAMC	3/21/12	N
Richardson, Tyronda	CJ	MS	8/19/05	ANCC Family 7/8/05	Y	Y	10/22/12	12/8/10	Anita Basu Jackson VAMC	N	N
Robinson, Cheryl	CJ	MS	3/14/97	ANCC Family 12/1/96	Y	Y	4/19/13	12/8/10	Jessie Crawford Moorefield Charlotte Scott-Bennett Jackson VAMC	3/14/12	N
Shegog, Miranda	NC	MS	9/26/11	ANCC Family 7/14/11	Y	Y	Left Jackson 6/23/12- CA still in effect	2/7/12	Kent Kirchner James Lockyer Jackson VAMC	N	N

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Shirley, Sara	C	AR	2/27/96	ANCC Adult 4/1/89	Y for Rx authority[6]	Y	6/7/12	6/7/12	Jessie Crawford Moorefield (Spencer) Jackson VAMC	2/22/11	N
Speed-Brockman, Jean	C	MS	11/27/95	ANCC Family 12/1/97 and Adult 12/1/95	Y	Y	3/22/13	12/7/10	Jessie Crawford Moorefield Donald Butcher (Locums) no longer employed Jackson VAMC	6/26/12	N
Stringer-Bell, Nikeba	CJ	MS	12/4/98	ANCC Family 12/1/96	Y	Y	11/8/12	12/7/10	Jessie Crawford Moorefield Jackson VAMC	2/27/13	N
Sutton, Debra	C	MS	9/21/04	ANCC Family 9/1/04	Y	Y	11/26/12	12/17/10	Jessie Crawford Moorefield Jackson VAMC	4/9/13	N
Thomas-Wolf, Dwan	CJ	MS	2/22/00	ANCC Family 8/1/99	Y	Y	11/6/12/	12/7/10	Jessie Crawford Moorefield Jackson VAMC	4/15/11	N
Thompson, Carol	CJ	MS	11/28/94	ANCC Adult 1/11/92	Y	Y	3/17/13	12/9/10	Jessie Crawford Moorefield Jackson VAMC	10/21/00	N

1 Penny Hardwick: NP was grandfathered prior to obtaining IA license on 4/10/13. Per VHA Directive NP would have required a CA for prescriptive authority under her grandfathered status. Once she obtained IA license she no longer required a CA.

2 William Hubbard: NP required CA under MS license, which NP had. CA no longer required since 1/18/13 under IA license.

3 William Hubbard and Barbara Kendrick: Physician Collaborator was a Locum Tenens and is no longer employed at the Jackson VAMC. Collaborative Agreement is thus not in effect.

4 Linda Mack: NP was grandfathered. Per VHA Directive would have required a CA for prescriptive authority under her grandfather status. However, NP did not have CA prior to 3/22/13.

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5 Kathleen McKinney: NP required to have CA per OH license. However, she did not have CA prior to 4/29/13. The CA signed by NP and MD on 4/29/13 has yet to be approved by the OH Nursing Board.											
6 Sara Shirley: NP required CA for prescriptive authority per AR license. She has prescriptive authority and DEA license but CA only in effect since 6/7/12. Prior to that date there is no evidence of a CA.											

Attachment C

Memorandum

Subject	Date
Revised Policy Regarding the Federal Government Practitioners Program (FEDDOC) (DFN: 601-04)	JUL 31 2012

To	From
Special Agents in Charge Assistant Special Agents in Charge Diversion Program Managers Diversion Group Supervisors	Joseph T. Rannazzisi Deputy Assistant Administrator Office of Diverison Control

The purpose of this memorandum is to clarify the Office of Diversion Control's (OD) policy regarding the Drug Enforcement Administration (DEA) Federal Government Practitioners Program (FEDDOC). FEDDOC practitioners are individuals who are direct hire employees of a Federal government agency (not contract practitioners) and are eligible for a fee exemption as set forth in 21 Code of Federal Regulations (C.F.R.) § 1301.21(a)(2). DEA has a longstanding policy regarding FEDDOC practitioners that permits a DEA registration be issued to the practitioner in one state as long as that person maintains a valid professional license in any state. This memorandum reaffirms the FEDDOC policy providing the following criteria are met:

- The FEDDOC practitioner's registered business address must be the official place of business.
- A FEDDOC registration can only be used for official duties on behalf of the Federal agency.
- Whenever a FEDDOC practitioner changes his or her official place of business, he or she must request a modification of registration pursuant to 21 C.F.R. § 1301.51, to reflect the location at which he or she is currently practicing.
- A FEDDOC practitioner must maintain a valid and current professional license. If the practitioner holds a professional license in a state that requires two licenses, then the practitioner must keep both licenses active and current only if the registered address is in the same state as the licenses, in order to be in compliance with that state.

The following Federal agencies are current participants in DEA's FEDDOC Program:

BOP - Bureau of Prisons
CDC - Centers for Disease Control and Prevention

DHS - Department of Homeland Security
DOJ - Department of Justice
FAA - Federal Aviation Administration
FDA - Food and Drug Administration
HHS - Health and Human Services
IHS - Indian Health Services
NASA - National Aeronautics and Space Administration
NCI - National Cancer Institute
NIH - National Institutes of Health
NIMH - National Institute of Mental Health
NOAA - National Oceanic and Atmospheric Administration
PHS - Public Health Services
USDA - United States Department of Agriculture
USPS - Unites States Postal Service
VA - Department of Veterans Affairs
U.S. Capitol Physician's Office
White House

If a FEDDOC practitioner wants to maintain a separate DEA registration for a private practice, which would include prescribing for private patients, he or she must be fully licensed to handle controlled substances by the state in which he or she is located pursuant to 21 C.F.R. § 1306.03(a). Under these circumstances, a FEDDOC practitioner is not eligible for the fee exemption under 21 C.F.R. § 1301.21(a)(2), to conduct his or her private practice and must pay DEA's registration fee.

Any questions regarding the FEDDOC Program may be addressed to the Registration and Program Support Section at (202) 307-7994.

- The NP functional statement, qualification standards, and dimensions of practice of the facility must be revised to be consistent with national policy per VA Handbook 5005 appendix G6.

- The Medical Center must complete a clinical care review of a random sample of patient care records for the NPs, who were prescribing controlled substances outside of the authority granted by their license. This review should focus on patients who were actually prescribed controlled substances. If any clinical issues are identified, the review should be expanded.

Facility policies and bylaws concerning the practice of NPs should be updated, to reflect VA national policies and the licensure and DEA requirements for this profession. Functional statements should be updated to reflect all current regulations.

VI. A listing of any violation or apparent violation of any law, rule, or regulation

The team substantiated that former Medical Center leadership directed NPs to practice under clinical privileges as LIPs, without regard to VHA policy or whether they were licensed as independent practitioners; did not ensure that the clinical practice of NPs was appropriately monitored by either their Physician Collaborators or through credentialing and privileging processes; and directed NPs to prescribe controlled substances using the institutional DEA registration with suffix, without regard to whether they were granted such prescriptive authority by their licenses or were required by their licensing board to prescribe under individual Federal DEA registration. The team also substantiated that Medical Center leadership requested PCP physicians to write controlled substances prescriptions for patients of the NPs based on a records review alone, without first conducting a face-to-face patient examination, under the belief that they were "covering physicians," and that some PCP physicians did so. These facility policies and practices violated the following Federal laws, rules, regulations and VA policies, as well as state licensing rules and regulations for collaborative agreements and controlled substances prescribing:

- The Controlled Substances Act, 21 U.S.C. § 823(f) (DEA registration requirements);

- DEA regulations, 21 CFR § 1306.03(a)(1)-(2) (Persons entitled to issue prescriptions);

- VA Handbook 5005, Part II, Appendix G6/27 (March 17, 2009), Nurse Qualification Standard VHA Handbook 1100.19, Credentialing and Privileging;

- VHA Directive 2008-049, Establishing Medication Prescribing Authority for Advanced Practice Nurses (August 22, 2008);

- VHA Directive 2012-030, Credentialing of Health Care Professionals;

- VHA Directive 2010-027, VHA Outpatient Scheduling Processes and Procedures (2010);

- VHA Updated Bylaws Template; and

- State licensing laws relating to collaborative agreements and controlled substances prescribing authority.

VII. Description of Any Actions to be Taken as a Result of the Investigation

No changes in national agency rules, regulations, or practices will be taken as a result of this investigation. Substantiation of the Whistleblower's allegations uniformly stem from the Medical Center's institutional failure to adhere to/or enforce current Federal laws and VA rules, regulations, and policies, as noted throughout the report. However, the team found that the facility's new leadership had taken some corrective measures to remedy past practices and prevent them from recurring. Leadership, under whom the noted non-compliant practices occurred, had already left the facility, and in some cases, the Department. VHA will be responsible for ensuring the facility completes the following recommended actions:

- Medical Center leadership must immediately correct the erroneous declaration that all NPs will practice as LIPs.

- Medical staff bylaws must be amended to indicate that NPs are considered LIPs only when their state licensure permits.

- Medical Center leadership must immediately implement scopes of practice versus clinical privileges for NPs, who are not permitted to practice as LIPs.

- Medical Center leadership must immediately ensure that all NPs, who require collaborative agreements, in fact have them, and that they are approved by the NP's respective state licensing board.

- Medical Center leadership should ensure the equitable distribution of collaborative agreements among physicians, and a reasonable limitation should be placed on the number of collaborative agreements for any one physician. If a state's Nursing Practice Act establishes a limitation on the number of collaborative agreements that a collaborating supervising physician may have with an NP at any one time, then the Medical Center needs to comply with such requirements.

- Medical Center leadership should eliminate use of Locum Tenens physicians in the PCU to the extent possible.

- Locum Tenens physicians should not be Physician Collaborators because of their short tenure.

- Medical Center leadership must immediately implement a process to ensure that appropriate monitoring of NP practice by Physician Collaborators occurs and is documented in accordance with state licensure requirements.

- Medical Center leadership must continue to aggressively work to hire permanent full-time physicians for the PCU, to obtain an NP:MD ratio of 1:1. Once an adequate number of physicians are hired, the Medical Center should reduce panel sizes for NPs to meet VHA guidelines.

- Medical Center leadership should consult the Office of Workforce Management and Consulting in VA Central Office to ensure they are utilizing all available resources to recruit primary care physicians.

- Medical Center leadership should eliminate the use of Ghost Clinics. All clinics must have an assigned provider.

- Medical Center leadership should eliminate the use of overbooked and double booked appointments to the extent possible. The Medical Center needs to implement the principles of open access scheduling, which means patients receive care when and where they want or need it, including on the same day, if requested.

- The Medical Center must convert six-part credentialing and privileging folders to the electronic VetPro system, as required by VHA leadership.

- VISN 16 leadership should arrange for an external clinical quality review of all primary care delivered at the Medical Center, particularly in light of the evidence that electronic View Alerts are often not being reviewed by physicians in a timely fashion and NPs were practicing outside the scope of their licensure. The Medical Center should conduct a clinical care review of a representative sample of the patient care records for all 42 NPs, as well as all physicians, who worked in the PCU from January 1, 2010, to present. The VISN should work with Medical Center leadership to determine the sample size needed to ensure that the quality of care delivered by all these providers was appropriate. If any clinical care issues are identified, the facility should consider expanding the sample. Specific cases involving unresolved questions as to quality of care should be referred to the Office of the Medical Inspector for further investigation.

- VISN 16 leadership should actively assist the Medical Center to implement these recommendations (and any others it deems necessary to ensure quality care is consistently rendered and available to PCU patients) through an approved action plan; and be responsible for submitting the action plan to the Under Secretary for Health along with periodic status reports (through to completion of all items).

- VHA should consider issuing an IL to reinforce across the system the need for compliance with both NP state licensure requirements and with national policies on NP credentialing, privileging, and scopes of practice. Such guidance should identify Regional Counsels as an important resource for the facilities as they review program compliance requirements.

- To determine whether Medicare home health certification/forms are/were being appropriately completed by the PCU providers, VHA should task the appropriate VHA offices, e.g., the VHA Office of Business Compliance and Integrity and the Office of Patient Care Services, Home Health Program, to work together to conduct a random check of PCU patient charts to determine if any Medicare forms are present, and if so, whether they were completed appropriately. Such findings need to be reported to the Under Secretary for Health, who will then need to consider if any follow-up action is necessitated. Additionally, facility leadership should consider development of a training and educational module for completion of these forms to ensure PCU and other staff are aware of CMS compliance requirements.

- The three NPs who have not yet received their individual DEA certificates should be encouraged to obtain these as soon as possible. Until that time, they are not writing for controlled substances, and are relying on the collaborating physicians to write for prescriptions as necessary.

- The NP functional statement, qualification standards and dimensions of practice of the facility must be revised to be consistent with national policy per VA Handbook 5005 appendix G6.

- The facility must complete a clinical care review of a random sample of the patient care records for the NPs who were prescribing controlled substances, outside of the authority granted by their license. This review should focus on patients who actually were prescribed controlled substances. If any clinical issues are identified the review should be expanded.

- Facility policies and bylaws concerning the practice of NPs should be updated, to reflect VA national policies and the licensure and DEA requirements for this profession. Functional Statements should be updated to reflect all current regulations.